immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,
and
(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

a1

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, each such immunogen so administered being hereafter referred to as an "early" immunogen regardless of its time of administration in the latter schedule(s),

where at least one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where at least one of said early immunogens is one other than BCG

or pertussis immunogen, and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early infectious disease-causing organism-associated immunogens is administered to the subject at about the same dates, relative to the date of birth as it was administered to the mammals in said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

a1

2 (amended). The method of claim 1 where the first dose of at least one early immunogen is given according to at least one screened schedule starting at less than 42 days after birth.

a2

5 (amended). The method of claim 2 where at least two immunogens are administered according to said subject schedule, and such immunogens include (1) a first immunogen which was given prior to 42 days after birth to said groups, and (2) a second and different immunogen which is an early immunogen.

a3

7 (amended). The method of claim 6 where said second immunogen is given in the subject schedule starting after 41 days after birth.

a4

9 (amended). The method of claim 8 where the first dose of said second immunogen is given before 180 days after birth in the subject schedule.

a5

11 (amended). The method of claim 1 further comprising (III) screening said subject, during or after receipt of said subject schedule, for the development of diabetes.

12 (amended). The method of claim 11 where subjects receiving said the subject schedule are used to estimate the immunization related risk of developing diabetes.

13 (amended). The method of claim 12 where the incidence of diabetes is calculated in a group of subjects receiving said

subject schedule.

14 (amended). The method of claim 4 further comprising (III) screening said subject, during or after receipt of said subject schedule, for the development of diabetes.

15 (amended). The method of claim 14 where said subjects receiving said subject schedule are used to estimate the immunization-related risk of developing diabetes.

16 (amended). The method of claim 15 where the incidence of diabetes is calculated in a group of subjects receiving said subject schedule.

a5

17 (amended). The method of claim 10 further comprising (III) screening said subject, during or after receipt of said subject schedule, for the development of diabetes.

18 (amended). The method of claim 17 where said subjects receiving said subject schedule are used to estimate the immunization-related risk of developing diabetes.

19 (amended). The method of claim 18 where the incidence of diabetes is calculated in a group of subjects receiving said subject schedule.

26 (amended). The method of claim 4 where the first dose of at least one immunogen is given according to at least one of the screened immunization schedules starting at less than 28 days after birth.

27 (amended). The method of claim 10 where the first dose of at least one immunogen is given according to at least one of the screened immunization schedules starting at less than 28 days after birth.

a6

28 (amended). The method of claim 4 where the first dose of at least one immunogen is given according to at least one of the screened immunization schedules starting at less than 14 days after birth.

29 (amended). The method of claim 10 where the first dose of at least one immunogen is given according to at least one of

the screened immunization schedules starting at less than 14 days after birth.

30 (amended). A method of immunizing a mammalian subject while reducing the risk of said subject thereby developing at least one chronic immune-mediated disorder, which comprises

(I) (a) immunizing a first group of mammals with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule,

(b) immunizing at least a second group of mammals with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, the first and second groups being of the same species, and

(c) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups,

as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism-associated immunogen given to both groups is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, each such immunogen so administered being hereafter referred to as an "early" immunogen regardless of its time of administration in the latter schedule(s),

where at least one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where at least one of said early immunogens is one other than BCG or pertussis immunogen,

and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early, infectious disease-causing organism-associated immunogens is administered to the subject at about the same dates, relative to the date of birth as it was administered to the mammals in said lower risk screened immunization schedule, resulting in a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

31 (amended). The method of claim 30 where at least one early immunogen administered according to the lower risk screened schedule and the subject third schedule is a hepatitis B immunogen.

32 (amended). The method of claim 30 where the hepatitis B immunogen is a killed immunogen administered prior to 42 days after birth, and at least one further immunogen is administered after 41 and before 180 days after birth in a screened schedule, and said further immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA

NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, cocidiomycosis, schistosomiasis, and malaria immunogens.

33. The method of claim 1 where said mammals in the screened schedule are randomly assigned to the groups and said immunization schedules are part of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

34. The method of claim 4 where said mammals in the screened schedule are randomly assigned to the groups and said immunization schedules are part of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

35. The method of claim 10 where said mammals in the screened schedule are randomly assigned to the groups and said immunization schedules are part of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

45 (amended). The method of claim 1 where the screened schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

46 (amended). The method of claim 4 where the screened schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

47 (amended). The method of claim 10 where the screened schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

~~48~~ 51 (amended). The method of claim 1 where the screened schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

~~49~~ 52 (amended). The method of claim 4 where the screened schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

53 (amended). The method of claim 10 where the screened schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

Please add the following new claims:

59 (new). The method of claim 1 where at least one comparison (b) is made at least two months after first administration of said immunogen to said mammals.

60 (new). The method of claim 1 where at least one comparison (b) is made at least 15 weeks after first administration of said immunogen to said mammals.

61 (new). The method of claim 1 where at least one comparison (b) is made at least 32 weeks after first administration of said immunogen to said mammals.

62 (new). The method of claim 1 where at least one comparison (b) is made at least 36 weeks after first administration of said immunogen to said mammals.

63 (new). The method of any one of claims 1-29, 33-58 where at least one comparison (b) is made at least one year after said first administration.

64 (new). The method of any one of claims 30-32 where at least one comparison (c) is made at least one year after said first administration.

65 (new). The method of claim 1 where said subject immunization schedule is identical to said lower risk screened immunization schedule.

66 (new). A method of immunizing a mammalian subject while reducing the risk of said subject thereby developing at least one chronic immune-mediated disorder, which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with

one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, each such immunogen so administered being hereafter referred to as an "early" immunogen regardless of its time of administration in the latter schedules,

where at least one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where at least one of said early immunogens is one other than BCG or pertussis immunogen, and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early infectious disease-causing organism-associated immunogens is first administered to the subject at a date earlier, relative to the date of birth of the subject, than the relative date it was first administered to mammals in said higher risk screened immunization schedule.

64 ~~67~~ (new). The method of claim ~~66~~ 63 where said early immunogen is first administered to the subject according to the subject schedule at a date earlier or about the same as, relative to birth, the date of first administration of that immunogen to mammals according to the lower risk screened schedule.

65 ~~68~~ (new). A method of immunizing a mammalian subject while reducing the risk of said subject thereby developing at least one chronic immune-mediated disorder, which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or

more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

a9

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, each such immunogen so administered being hereafter referred to as an "early" immunogen regardless of its time of administration in the latter schedules,

where one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where at least one of said early immunogens is one other than BCG

or pertussis immunogen, and

(II) immunizing said subject according to a subject immunization schedule, according to which, during a first period corresponding to the first 112 days after birth, at least one of said early infectious disease-causing organism-associated immunogens is administered (i) at least as often as during said first period according to said lower risk screened immunization schedule, or (ii) more often than during said first period according to said higher risk screened immunization schedule.

66 ~~69~~ (new). The method of claim 1 where said subject of (II) is immunized according to said subject schedule, during the period corresponding to the first 112 days after birth, with at least one early immunogen at least as often during said period as said immunogen was administered to said mammals according to the lower risk screened immunization schedule, or (ii) more often than during said first period according to said higher risk screened immunization schedule.

67 ~~70~~ (new). The method of claim ~~68~~ 65 where in said subject schedule, during a second period corresponding the first 175 days after birth, at least one of said early infectious disease-causing organism-associated immunogens is administered at least as often, as during said third period in said lower risk screened immunization schedule or more often than during said third period according to said higher risk screened immunization schedule.

68 ~~71~~ (new). The method of claim ~~68~~ 65 where both (i) and (ii) apply.

~~72~~ 69 (new). The method of claim 1 in which more than two immunization schedules are screened, each in its own group of mammals.

~~73~~ 70 (new). The method of claim 1 where at least one comparison (b) is made at least one year after said first administration and in which the subject schedule is a